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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
09/853,544	05/10/2001	Miguel S. Barbosa	10624-051	7460				
20583 JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017	7590 10/30/2007		<table border="1"><tr><td>EXAMINER</td></tr><tr><td>PAK, MICHAEL D</td></tr></table>		EXAMINER	PAK, MICHAEL D		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/853,544	<b>Applicant(s)</b> BARBOSA ET AL.	
	<b>Examiner</b> Michael Pak	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-16, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16, 26-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-12 and 17-25 have been cancelled. Claims 13-16 and 26-27 are pending.
2. Applicant's arguments filed 29 November 2005, have been fully considered but they are not found persuasive.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13, 15-16 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that a specification that discloses the specific nucleotide sequence which satisfies the written description requirement. However, essential feature of the claimed method is the discovery that nucleic acid sequences which have not been identified by function (i.e. orphan proteins) such as SEQ ID NO:1 can be used

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as regulated sequence of the estrogen modulation but the function of SEQ ID NO:1 is not known. For example at the time of the invention, NCI-CGAP (accession number AA747315, 1999), discloses a nucleic acid sequence which is identical to the claimed SEQ ID NO:1 but NCI-CGAP is a sequence which resulted from human genome sequencing and the function of the sequence is not known. Orphan proteins whose function is not known. Thus, the disclosure of an orphan nucleic sequence is not sufficient disclosure where the function of the protein or nucleic acid is known.

Applicants argue that the specification describes several species to provide description for a genus and therefore meets the standard established for adequate written description of sequences by the Federal Circuit. However, essential feature of the claimed method is the discovery of nucleic acid sequences which have not been identified by function such SEQ ID NO:1 can be used as regulated sequence of the estrogen modulation but the function of SEQ ID NO:1 is not known. For example at the time of the invention, NCI-CGAP (accession number AA747315, 1999), discloses a nucleic acid sequence which is identical to the claimed SEQ ID NO:1 but NCI-CGAP is a sequence which resulted from human genome sequencing and the function of the sequence is not known. There is lack of written description for a method for genus of nucleic acid whose function is not known. The ability to regulate the nucleic acid does not provide sufficient written description for the nucleic acid whose function is not known. Furthermore, the claims are drawn to the generically to all ERM and not the specifically disclosed sequences.

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4. Claims 13-16 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a a method of using estrogen receptor marker with function, does not reasonably provide the full scope of enablement for a method of using an estrogen receptor marker which is an orphan protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The reason for the rejection has been set forth in the previous office actions.

Applicants argue that working example 4 is enabled and thus since the specification discloses at least one invention that is enabled and is within reasonable scope. However, the claims are not within a reasonable scope and the breadth of the method in most of the claims is drawn generically to ERM method and not to specific species. Furthermore, the specific species are drawn to orphan proteins whose function is not known and thus is not enabled.

Applicants argue that the rejection is unduly focused on the protein structure and function of the ERM. However, the ERM encompass orphan proteins whose function is not known. The methods disclosed in the examples do not teach the function of the orphan proteins.

***Claim Rejections - 35 USC § 102***

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5. Claims 13,15-17 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Mendelsohn et al.(US 5,728,534).

The reason for the rejection has been set forth in the previous office actions.

Applicants argue that Mendelsohn does not teach the method of identifying selective estrogen receptor modulators using at least one endogenously-expressed ERM in the cells. However, the claims are not limited to endogenously-expressed ERM in the cells because no such claim limitations are in the claims. Furthermore, claims are generically drawn to ERM which is not defined and is met by the teaching of Mendelsohn. Applicants are arguing as if the claims are narrowly drawn whereas the claims are broadly drawn to any ERM method.

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached from 8:30 to 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
26 October 2007